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09/930,104	08/14/2001	Allan Leslie Friedman	2640/1G826US1	9867

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EXAMINER
WEST, JEFFREY R

ART UNIT	PAPER NUMBER
2857	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,104	FRIEDMAN ET AL.	
	Examiner	Art Unit	
	Jeffrey R. West	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *33-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 January 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

On page 16, line 28, "logic circuit 106" should be ---logic circuit 104---.

On page 17, line 2, Applicant refers to "104" as a line while 6b shows "104" as "Phase Detection Logic".

Appropriate correction is required.

Claim Objections

2. Claims 1, 4, 17, and 20 are objected to because of the following informalities:

In claim 1, line 7 and claim 17, line 4, "obtaining magnitude impedance data and impedance phase data" should be either ---obtaining magnitude impedance data and phase impedance data--- or ---obtaining impedance magnitude data and impedance phase data---. Similar changes should be made to claims 4 and 20.

Also, in claim 20, references to "impedance magnitude data" and "impedance phase data" should be claimed as "the impedance magnitude data" and "the impedance phase data" similar to the language in claim 4.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is considered to be vague and indefinite because it first recites, "obtaining magnitude impedance data and impedance phase data" but subsequently recites, "comparing the impedance data". Stated this way, it is unclear to one having ordinary skill in the art as to whether it is the "magnitude impedance data," "impedance phase data," or both, that is being compared.

Claim 17 is similarly rejected under 35 U.S.C. 112, second paragraph, because it includes limitations for "obtaining magnitude impedance data and impedance phase data for one of a new blade and a blade having known characteristics" but subsequently recites, "comparing . . . to the impedance data of one of the new blade and the blade having known characteristics".

Claims 6 and 22 are rejected as being vague and indefinite because they include a limitation for "evaluation of a continuousness of the data obtained." This limitation is considered to be vague because it is unclear to what "data obtained" is being referred to since "lowest impedance", "maximum phase" and "blade resonance frequency" data is presented. None of these types of data are defined as being "the data obtained". It is assumed that for the prosecution of the application, "data obtained" refers to "impedance data obtained" and therefore, to correct this indefinite limitation, "of the data obtained" should be ---of the impedance data obtained---.

Claims 7 and 23 are rejected under 35 U.S.C. 112, second paragraph, for several reasons.

First, the limitation of a "lower excitation level" is considered to be indefinite because it is unclear to one having ordinary skill in the art to the scope of the relative term "lower" (i.e. lower with respect to what?). Also, the claim is providing a "lower excitation level" without any previous excitation level. Therefore, it is unclear as to what this excitation level is lower.

Second, claims 7 and 23, line 8, contain a limitation reciting "a lower excitation level". In this mention of a "lower excitation level" it is unclear to one having ordinary skill in the art whether this "lower excitation level" is the same as the "lower excitation level" presented in line 4. It is also unclear to one having ordinary skill in the art to which "lower excitation level" the recitation of "the lower excitation level" refers in line 10.

Finally, claims 7 and 23 recite, "if impedance data at a lower excitation level reveals one of an unchanged minimum impedance magnitude" and "if any impedance data sweep at a lower excitation level reveals one of an unchanged minimum impedance magnitude". These limitations are considered to be vague and indefinite because it is unclear to one having ordinary skill in the art as to what impedance magnitude is unchanged, what it is unchanged with respect to, and over what type of interval it is unchanged.

Claim 7 is further rejected under 35 U.S.C. 112, second paragraph, because it contains limitations for displaying messages on "the liquid crystal display" without a previous mention of any "liquid crystal display".

Claim 23 is further rejected under 35 U.S.C. 112, second paragraph, because it recites the confusing language of "a higher minimum impedance."

Also in claim 23, the limitation reciting, "any impedance data sweep" is unclear because there is no previous mention of an "impedance data sweep" or any "impedance data sweeping". Since there is no step for performing a sweep, it is unclear how the conditions of the sweeps can be determined.

Claims 13, 14, 29, and 30 are rejected under 35 U.S.C. 112, second paragraph because in the limitation for calculating "differences between impedance magnitudes" it is unclear to which magnitudes the limitation is referring. For example, parent claims 7 and 23, include "a minimum impedance magnitude which is less than a minimum impedance magnitude obtained at a higher excitation level" as well as "an unchanged minimum impedance magnitude or a [higher] minimum impedance at the lower excitation level which is higher than the minimum impedance magnitude obtained at the higher excitation level." Because several impedances are defined, it is unclear to one having ordinary skill in the art what impedance magnitudes are having differences calculated.

Claims 2-5, 8-12, 15, 16, 18-21, 24-28, 31, and 32 are rejected under 35 U.S.C. 112, second paragraph, because they incorporate the lack of clarity present in their respective parent claims.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claim 1, 2, 4, 6, 17, 18, 20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,042,460 to Sakurai et al. in view of JP Patent No. 06-003305 to Senda et al.

Sakurai discloses an ultrasonic treating apparatus with a device for inhibiting drive when the ultrasonic element is determined to be defective comprising applying a drive signal to an ultrasonic hand piece/blade using an ultrasonic generator (column 3, lines 7-19), obtaining impedance data for the hand piece/blade (column 3, lines 25-28) comparing the impedance data to determine whether the impedance data is within acceptable limits (column 4, lines 35-39) and if the impedance is within acceptable limits, displaying a message on a display of the generator (column 4, lines 40-42).

Further, since Sakurai discloses applying driving electric power, it is considered inherent that the electric power signal has a current level and a voltage level since power is a function of current and voltage.

As noted above, the invention of Sakurai teaches many of the features of the claimed invention and while the invention of Sakurai does teach determining incorrect operation of transducer device, Sakurai discloses determining incorrect operation due to degradation of the device rather than determining a physical defect that causes the incorrect operation.

Senda teaches a method for non-destructively inspecting a piezoelectric element for a micro-crack comprising obtaining impedance data for a known/ideal element (0013, lines 1-4) applying a drive signal for exciting the piezoelectric element over a predetermined frequency range and obtaining impedance magnitude and impedance phase data of the tested element (0021, lines 1-13), at a plurality current and voltage excitation levels (0010), and comparing the impedance of the element under test to the known element impedance data to determine the correctness of operation (0021, line 13 to 0022, line 7 and 0028). Senda also teaches comparing a magnitude of a lowest impedance (i.e. impedance at resonance) (0019) to the expected waveform to determine non-linearity (0010, 0025, and 0028).

It would have been obvious to one having ordinary skill in the art to modify the invention of Sakurai to teach a method for determining a crack in the device as compared to a known/ideal device, as taught by Senda, because the combination would have provided a method for determining the occurrence of a physical defect

thereby allowing the user to correctly diagnose and correct the problem and, as suggested by Senda, provided precise diagnostics quickly, automatically, and without destroying the device under test (0005-0007).

Although the invention of Sakurai and Senda discloses performing the comparison to determine a crack in the transducer rather than the blade itself, since the blade and the transducer are attached a change in impedance due to a crack in the blade would also correspond to the change in impedance observed by the current method (See, for example, page 4, lines 7-16 of the Background of the instant invention that describes the grouped frequency response of the transducer and blade and the correlation between the electric parameters of the transducer and the blade response). Therefore, the combination of Sakurai and Senda operates in a method that determines the change in impedance indicating a crack in the transducer or the connected blade.

7. Claims 3, 5, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai in view of Senda and further in view of U.S. Patent No. 6,019,775 to Sakurai (Sakurai '775).

As noted above the invention of Sakurai and Senda teaches many of the features of the claimed invention including exciting the hand piece across a predefined frequency range and obtaining impedance data at a plurality of excitation levels, but does specify that the frequency range be from 50 to 60 kHz or that the excitation levels be in the range of 5mA to 50mA.

Sakurai '775 teaches an ultrasonic operation apparatus for performing treatment through utilization of an ultrasonic oscillator comprising a handpiece, serving as a surgical tool, and an apparatus body including a power source unit for supplying electric power to the handpiece (abstract). Sakurai '775 teaches that the handpiece includes a signal generating unit for generating a signal corresponding to a resonant frequency inherent in the ultrasonic element and the probe (abstract). Sakurai '775 also teaches that in ultrasonic surgery tools the oscillator is designed to generate a resonant frequency corresponding to the specific handpiece (column 1, lines 31-47) as well as that the excitation current of the specific handpiece varies based upon the oscillator employed (column 9, lines 41-56).

It would have been obvious to one having ordinary skill in the art to modify the invention of Sakurai and Senda to include sweeping across a predetermined frequency range of 50 to 60 kHz and exciting the handpiece at a current in the range of 5mA to 50mA because Sakurai suggests that each handpiece requires a different frequency sweep range (column 1, lines 31-47) and excitation current (column 9, lines 41-56) based upon the specific makeup of the device being used. Therefore one with ordinary skill in the art would select whatever range is required for the user's specific device, such as 50 to 60 kHz or 5mA to 50mA, as necessary to implement the specific device in its required operation. (See also, for example, U.S. Patent No. 6,391,042 to Cimino, column 1, lines 28-37, U.S. Patent No. 5,406,503 to Williams Jr. et al., column 3, lines 50-60, and U.S. Patent No. 6,387,109 to Davidson

et al., column 5, lines 6-26, which teach different ultrasonic devices requiring different frequency ranges and excitation currents for their individual operation.)

Response to Arguments

8. Applicant's arguments with respect to claims 1-32 have been considered but are moot in view of the new ground(s) of rejection.

The following arguments, however, are noted.

First, with respect to the objections to the specification, Applicant has changed "logic circuit 104" to "logic circuit 106" instead of changing the informality in the next line of "digital code on line 104" to "digital code on line 106".

Applicant first argues, with respect to the rejection of claim 6 under 35 U.S.C. 112, second paragraph, that "the Examiner has stated that this claim is indefinite because it recites a limitation for 'evaluation of a continuousness of the data obtained'. In response to this rejection, Applicants respectfully assert that the evaluation is of all the data that is obtained, i.e., the 'lowest impedance', the 'maximum phase', and the 'blade resonance frequency'. As a result, Applicants respectfully assert that this claim is clear."

The Examiner maintains that one having ordinary skill in the art would not interpret the limitation of "the data obtained" to mean the "lowest impedance", "maximum phase" and "blade resonance frequency" since these three values are not referred to as "data" nor is there any limitation for "obtaining" these values. Since

Applicant as indicated that "the data obtained" is to mean "lowest impedance", "maximum phase" and "blade resonance frequency", it is suggested that in order to avoid any confusion, Applicant change "an evaluation of a continuousness of the data obtained" to ---an evaluation of a continuousness of the magnitude of a lowest impedance, the maximum phase, and the blade resonance frequency.

Applicant then argues, with respect to claims 13, 14, and 30, that the Examiner has stated that the limitation 'calculating differences between impedance magnitudes' is unclear because it is not clear to which magnitudes the limitation is referring. In response to this rejection, the following is noted, the claim limitation establishes two comparisons which are performed. In this case, the differences of the impedance magnitudes are the comparisons that are preformed between the 'minimum impedance magnitude' and the 'minimum impedance magnitude obtained at a higher excitation level' as well as the 'minimum unchanged impedance magnitude' and the 'minimum impedance which is higher than the minimum impedance magnitude obtained at the higher excitation level.' Accordingly, Applicants respectfully assert that the claim limitations are clear."

The Examiner maintains that the recitation, in claim 13 for example, "wherein said excess heat is computed by calculating difference between impedance magnitudes" does not suggest to one having ordinary skill in the art that this step of "calculating differences" is the same determination made in "displaying a first message on the liquid crystal display, if impedance data at a lower excitation level

reveals a minimum impedance magnitude which is less than a minimum impedance magnitude obtained at a higher excitation level; and displaying a second message on the liquid crystal display, if impedance data at a lower excitation level reveals one of an unchanged minimum impedance magnitude or a minimum impedance at the lower excitation level . . ." Claim 13 is conveyed as a separate step and it would be unclear to one having ordinary skill in the art as to which magnitudes the limitation is referring.

Applicant then argues the Examiner's assertion in the previous Office Action that the invention of Senda teaches calculation of impedance magnitude and impedance phase data stating, "the calculation of phase data in the present claimed invention involves the calculation of impedance phase for the hand piece/blade which is determined by calculation the difference in frequency of the anti-resonance (i.e., the frequency with maximum impedance) and the resonance (i.e., the frequency with minimum frequency). This aspect of the invention is set forth on page 13, lines 4-10 of the specification. In the *Senda* et al. reference, the phase that is measured is the difference between the frequency characteristic and/or voltage and current of the impedance of a piezo-electric element. This is a different measurement than the impedance phase measurement set forth and claimed in independent claims 1 and 17, which is based on values at maximum and minimum resonance frequencies."

The Examiner asserts that claims 1 and 17 only recite "obtaining magnitude impedance data and impedance phase data" and while the claims are interpreted in

light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Therefore, Applicant's argument that the phase data measurement of Senda "is a different measurement than the impedance phase measurement set forth and claimed in independent claims 1 and 17, which is based on values at maximum and minimum resonance frequencies" is not persuasive. Senda's teaching for obtaining impedance phase data meets the invention as claimed in claims 1 and 17.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

U.S. Patent No. 6,391,042 to Cimino teaches a pulsed ultrasonic device and method as well as the conventional operating range of 20kHz to 60kHz.

U.S. Patent No. 5,406,503 to Williams Jr. et al. teaches a control system for calibrating and driving ultrasonic transducers including a power amplifier and transformer section that provides a maximum driving voltage of about 380 volts RMS with a maximum current of about 10 mA RMS.

U.S. Patent No. 6,387,109 to Davidson et al. teaches methods and a device for improving blood flow to the heart of a patient including a generator that applies a specific current to acoustically vibrate an assembly in the range of 20kHz to 100 kHz, preferably, 54 kHz to 56 kHz.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. West whose telephone number is (703)308-1309. The examiner can normally be reached on Monday through Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (703)308-1677. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0956.

jrw
April 1, 2004

MARC S. HOFF
SUPERVISORY PATENT EXAMINER
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